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10/551,024	09/29/2005	Menno Willem Jose Prins	NL 030339	8261

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EXAMINER	
HURST, JONATHAN M	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,024	PRINS, MENNO WILLEM JOSE	
	Examiner	Art Unit	
	JONATHAN M. HURST	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09/29/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/24/2009 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-14, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Connor et al. (US 6,481,453).

Regarding claim 1, O'Connor et al discloses a fluidic device for producing consecutive series of plurality of independent sample plugs, the device comprising: (See Abstract) a plurality of sample channels each of said plurality of sample channels having a sample fluid inlet (See Fig. 4A 314A-314N, 320A-320N, and Col. 12 Lines 34-38) said plurality of sample channels being adapted to be filled through said inlet with a

sample fluid to be-analyzed or treated in use of said device (See Col. 13 Lines 1-24 and Col. 5 Lines 9-11),

O'Connor et al discloses a flush fluid control means positioned to traverse said plurality of sample channels downstream the location where the sample fluid is analyzed or treated in said device (See Fig. 4B 313 and Col. 13 Lines 4-21), said flush fluid control means having flush fluid inlet means and flush fluid outlet means in communication with each of said plurality of sample channels and said flush fluid control means being adapted to control the fluid composition in said plurality of sample channels; and(Col. 13 Lines 4-15 where displacement of first fluid with second fluid by increase in pressure controls the fluid composition in channel)

O'Connor et al further discloses at least one individual threshold provided in each of said plurality of sample channels, (See Fig. 4A and Abstract where membrane 304 forms a threshold area above each channel and no two channels overlap the same threshold area and as such each threshold is individual to each said channel also See Col. 13 Lines 47-54 where valves are used as impedance regions)

It is noted that the device of O'Connor is fully capable of having the flush fluid control means operated to simultaneously produce consecutively arranged series of independent sample plugs in each of the plurality of sample channels if one so desired and such a recitation is an intended use of the device. A recitation directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art, if the prior art has the capability to so perform. The

recitation of a new intended use for an old product does not make a claim to that old product patentable. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Regarding claim 2, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein said fluid device is a microfluidic device, at least partly manufactured by micromachining methods. (See Abstract and Col. 1 Lines 32 -46)

Regarding claim 3 O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein said flush fluid control means controls said flush fluid content at said channel inlet by replacing a fixed amount of said sample fluid in said sample channels with flush fluid upstream of said fluid control means. (Col. 13 Lines 4-15 where there is a displacement of first fluid with second fluid by increase in pressure)

Regarding claim 4, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein said control means is a cross-over channel. (See Fig. 4A and 4B where control means 313 is a channel and crosses over channels 314A-314N and 320A-320N)

Regarding claim 5, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein the cross-over channel divides two arrays or

microchannels. (See Fig. 4B where the cross over channel at the least visibly divides to arrays of microchannels)

Regarding claim 6, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein said fluid inlet and fluid outlet means of said fluid control means are inlet an outlet channels. (See Fig. 4B inlet 310 and outlet 311 connected to channel 313)

Regarding claim 7, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein said inlet and outlet channels comprise valve means for controlling flush fluid communication through said inlet and fluid communication through said outlet channel (See Col. 13 Lines 4-6 and Col. 13 Lines 24-28)

Regarding claim 8, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein said device comprises further comprising pressure regulating means for controlling flush fluid communication through said inlet fluid communication through said outlet channel and fluid flow through said sample channels (See Col. 13 Lines 18-29 where valves are pressure regulating means)

Regarding claim 9, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein the at least one threshold being arranged in

said plurality of sample channels upstream of said flush fluid control means in the fluid flow direction of said sample fluid. (See Fig. 4A where membrane 304 is a threshold and Abstract where impedance region is a threshold)

Regarding claim 10, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein said is tuneable. (See Col. 8 Lines 18-25 where impedance is controlled depending on application and is thus tuneable)

Regarding claim 11, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device, wherein said threshold is in each of said channels is controlled by a physical constriction, a fluidophobic or hydrophobic effect, an electric field, a temperature or light excitation. (See Col. 7 Lines 38-46 where a constriction is used)

Regarding claim 12, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein said threshold is controlled by a common control for all channels. (See Fig. 4A where each threshold is found on a commonly controlled membrane 304)

Regarding claim 13, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein independent sample plugs are formed in

said sample channels by said control means. (See Col 5 Lines 29-31 and Col. 13 Lines 4-24)

Regarding claim 14, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein said flush fluid is a gas or an inert liquid. (See Col. 7 Lines 54-66 where second fluid is a flush fluid and can be a gas or liquid)

Regarding claim 16, O'Connor et al. discloses all the claim limitations as set forth above as well as the fluidic device wherein said fluidic device is selected from at least one of a diagnostic cartridge, a microfluidic chip, a lab-on-a-chip, a micro-total-analysis system, a biochip or a biosensor. (See Col. 1 Lines 21-32 and Col. 2 Lines 16-34 where biological material is analyzed and thus device is a biosensor)

4. Claims 17 and 21-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Manz et al. (US 6,540,896).

Regarding claim 17, Manz et al discloses a method of generating independent fluid samples in a fluidic device for producing consecutive series of plurality of independent sample plugs for multichannel analysis the method comprising : (See Abstract and Fig. 1D)

Filling simultaneously a plurality of sample channels through a sample fluid inlet, with a sample fluid to be analyzed or treated in said device; (See Fig. 3B sample

channels 322, 312, and 306 , Fig. 1D and 2A-2D where a plurality of channels are filled simultaneously with a sample to be analyzed)

Manz further discloses controlling a fluid composition in said plurality of sample channels via a flush fluid control means positioned to traverse said plurality of sample channels downstream the location where the sample fluid is analyzed or treated in said device, said flush fluid control means having flush fluid inlet means and flush fluid outlet means in communication with each of said plurality of sample channels, (See Fig. 3B Flush Fluid control means 318 and 304 also see Col. 4 Lines 30-40 and Fig. 1D where a plurality of consecutively arranged independent sample plugs are formed in a plurality of channels where flush fluid introduction controls fluid composition in sample channels)

Manz further discloses operating the flush fluid control means to simultaneously produce consecutively arranged series of independent sample plugs in each of the plurality of sample channels, (See Col. 4 Lines 30-40 and Fig. 1D where a plurality of consecutively arranged independent sample plugs are formed in a plurality of channels)

Manz further discloses flushing of a flush fluid control means with flush fluid such that the consecutively arranged series of independent sample plugs are formed in multiple channels each of the plurality of sample channels of said device said sample plugs being separated by said flush fluid. (See Figs. 2A-2D, Col. 4 Lines 16-65, and Fig.1D where the methods as described are used to form consecutive and discrete sample plugs in a plurality of channels by utilizing flushing of a flush fluid control means)

Manz further discloses the method wherein the flow of sample is stopped, reduced, or reversed, in said sample channels.

Regarding claim 21, Manz discloses all the claim limitations as set forth above as well as the method wherein said multichannel analysis is performed in a diagnostic cartridge, a microfluidic chip, a lab-on-a-chip, a micro-total-analysis system, a biochip or a biosensor. (See Abstract and Col. 9 Lines 29-60)

Regarding claim 22, Manz discloses all the claim limitations as set forth above as well as the method wherein said multichannel analysis is performed by a microfluidic device. (See Abstract)

Regarding claim 23, Manz discloses a computer-readable medium having embodied thereon a computer program for processing by a computer for generating consecutive series of independent fluid samples in a fluidic device for multichannel analysis the fluidic device comprising: (See Abstract and Col. 10 Lines 17-35)

Manz further discloses a code segment for filling simultaneously a plurality of sample channels each of said plurality of sample channels through a sample fluid inlet with a sample fluid to be analyzed or treated in said device;

Manz further discloses a code segment for controlling a fluid composition in said plurality of sample channels via a flush fluid control means positioned to traverse said plurality of sample channels downstream the location where the sample fluid is

analyzed or treated in said device, said flush fluid control means having flush fluid inlet means and flush fluid outlet means in communication with each of said plurality of sample channels;

Manz further discloses a code segment for operating the flush fluid control means to simultaneously produce consecutively arranged series of independent sample plugs in each of the plurality of sample channels,

Manz further discloses and a code segment for flushing of a flush fluid control means with flush fluid such that the consecutively arranged series of independent sample fluid plugs are formed in each of the plurality of sample channels of said device said sample plugs being separated by said flush fluid.

(See Fig. 1D, Fig. 2A-2D, Fig. 7, and Col. 10 Lines 17-35 where a plurality of channels are filled simultaneously with a sample fluid through an inlet, a flush fluid controls fluid composition in said channels, and there is a flushing of a flush fluid control means with flush fluid and subsequent formation of consecutively arranged sample plugs in a plurality of channels said plugs separated by said flush fluid.

It is noted that fluid movement (both sample and flush fluid) within the device is controlled at least in part by the operation of fluid pumps in the device said pumps and thus sample and flush fluids are controlled by a computer which must contain a program with code segments capable of causing a computer to perform the actions as stated above.)

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al. (US 6,481,453) in view of Kennedy (US 5,876,675)

Regarding claim 13 O'Connor et al. discloses all the claim limitations as set forth above but does not disclose wherein the said fluidic device is arranged inside a compact housing, said housing being a diagnostic cartridge.

Kennedy discloses a fluidic device arranged inside a compact housing (See Fig. 1, 2, and Col. 8 Lines 42-62, Col. 9 Lines 12-44 where microfluidic device 102 is

inserted into holder assembly), said housing being a diagnostic cartridge. (See Col. 2 Lines 26-4 and Col. 8 Lines 42-62 where device is used in diagnostic applications)

It would have been obvious to one of ordinary skill in the art at the time of invention to place the fluidic device of O'Connor in the structure of Kennedy because doing so protects the fluidic device and prevents fouling, interference, and other adverse effects in the operation of microfluidic devices with material transport systems. (See Kennedy Col. 2 Lines 28-44 and Col. 5 Llines13-25)

8. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manz et al. (US 6,540,896), and further in view of O'Connor et al. (US 6,481,453)

Regarding claim 18, modified Manz discloses all the claim limitations as set forth above as well as the method wherein said flush fluid control means having flush fluid inlet means and flush fluid outlet means (See Fig. 3B where flush fluid control means 318 has inlet and outlet) said method further comprising the acts of introducing sample liquid into said device through a sample fluid inlet into a plurality of channels, transporting said sample liquid across said flush fluid control means further into said channels until a threshold (See Figs. 2A-2D and Col. 4 Lines 15-51 where a liquid sample is transported through channels 204-210 across flush fluid means 200 until sample flow is reduced or stopped by reaching a threshold as described above)

Manz also discloses opening of said flush fluid inlet means and flush fluid outlet means flushing of said flush fluid control means with a flush fluid, transporting said sample liquid in said channels and said flush liquid in said flush fluid control means across said flush fluid control means further into said channels. (See Figs. 2A-2D where sample are transported across flush fluid control means 200 into sample channels 232-240 by flushing with a flush fluid)

Modified Manz et al. does not specifically disclose at least one individual threshold provided in each of said plurality of sample channels or the use of valves to control the opening and closing of said flush fluid inlet and outlet or

O'Connor et al. discloses the use of valves in microfluidic channels in order to control, including stopping and reducing, the flow of fluids in said microfluidic channels and create a series of sample plugs. (See Col. 5 Lines 19-24, Col. 7 Lines 39-45, and Col. 13 Lines 44-54)

It would have been obvious to one of ordinary skill in the art at the time of invention to provide valves, thresholds, in each of a plurality of sample channels as described by O'Connor in the method of Manz because valves are well known in the art to control the flow of a fluid in a channel and valves efficiently provide a means to reduce or stop the flow of fluids in the sample channels as is required by Manz. (See Manz Col. 4 Lines 44-52)

O'Connor et al. further discloses the use of valves to control the input and output of flush fluid in order to create sample plugs in a microfluidic device. (See Abstract and Col. 13 Lines 4-6 where a second fluid is a flush fluid)

It would have been obvious to one of ordinary skill in the art at the time of invention to use valves to control flush fluid introduction as described by O'Connor in the method of modified Manz by opening a valve because valves and their opening and closing of valves are well known in the art to control the flow of fluids in microfluidic devices as is required by modified Manz. (See Manz Abstract and Col. 6 Lines 30-37)

Regarding claim 19, modified Manz discloses all the claim limitations as set forth above but does not specifically disclose the method wherein a plurality of consecutive independent sample fluid plugs are generated by repeating said acts of opening of said flush fluid inlet means and flush fluid outlet means by means of said valve means flushing of said flush fluid control means with a flush fluid, transporting said sample liquid in said channels and said flush liquid in said flush fluid control means across said flush fluid control means further into said channels.

It is noted that once one independent sample plug is formed in each of a plurality of channels by opening of a flush fluid inlet means and flush fluid outlet means by means of a valve means flushing of said flush fluid control means with a flush fluid transporting a sample liquid in said channels and said flush liquid in said flush fluid control means across said flush fluid control means further into said channels as

described above it would have been obvious to one of ordinary skill in the art at the time of invention to repeat the stated process steps in order to create a plurality of consecutive sample plugs in a plurality of sample channels. (See Manz Figure 1D where a plurality of consecutive sample plugs are shown in a plurality of sample channels.) Furthermore it is noted that mere duplication of parts or process steps has no patentable significance, unless a new and unexpected result is produced, since it involves only routine skill in the art.

Regarding claim 20, modified Manz discloses all the claim limitations as set forth above as well as the method wherein after the step of flushing said flush fluid control means with a flush fluid, said flush-fluid inlet means and flush-fluid outlet means are re-closed by means of valve means or said flush fluid is put under pressure for transporting said sample fluid into said channels. (See Manz Fig. 7 and Col. 10 Lines 25-35 where a pump is used to transport flush fluid and as such must be placed under pressure)

Response to Arguments

9. Applicant's arguments filed 07/23/2009 have been fully considered but they are not persuasive.

Applicant argues on pages 13-17 that "the presently pending claims do not recite an "intended use" as contemplated by In re Schreiber. Rather, claims 1-16 define the features of the device, using functional language."

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. >In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997) (The absence of a disclosure in a prior art reference relating to function did not defeat the Board's finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference); see also In re Swinehart, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971);< In re Danly, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

It is the examiner's position that the device of modified O'Connor is fully capable of performing the actions as described in claims 1-16. The recitation of a control means, later defined to be a cross-over channel with valves (See instant claims 4 and 7) provides positively recited structure to said claimed apparatus. The recitations directed

to the actions in which said control means are intended to perform do define any structural elements which distinguish the apparatus over the prior art and merely recite non limiting actions which may be performed with said positively structural elements.

It is noted that many of the claim limitations directed to actions performed by said control means appear to be blocks of code which are intended to be run by a microprocessor (or similar) and are currently not claimed as being embodied on a computer readable medium and thus are not directed to any specific structure. Functional descriptive material such as computer programs and/or data structures not claimed as embodied in computer-readable media are descriptive material per se and are not statutory because they are not capable of causing functional change in the computer. Such claimed data structures do not define any structural and functional interrelationships between the data structure and other claimed aspects of the invention which permit the data structure's functionality to be realized. (See MPEP 2106.01(I)).

Applicant argues on pages 17-18 that the claims were not properly examined under 35 U.S.C. §112, paragraph 6. It is noted that the claims do not recite the phrase "means for" or step for" followed by functional language as is required for claims to invoking 35 U.S.C. §112, 6th paragraph. See MPEP §2181.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN M. HURST whose telephone number is

(571)270-7065. The examiner can normally be reached on Mon. - Thurs. 6:30-5:00; Every Fri. off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571)272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. H./

Examiner, Art Unit 1797

/Michael A Marcheschi/

Supervisory Patent Examiner, Art Unit 1797